

OC 1 7 2005

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Section XII: 510(k) Summary of Safety and Effectiveness
SAFE MEDICAL DEVICES ACT OF 1990
510(k) Summary

NAME OF FIRM: I.T.S. Implantat-Technologie-Systeme GmbH
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Lassnitzhoehe A - 8301
AUSTRIA

510(k) FIRM CONTACT: Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th St.
Prior Lake, MN 55372

TRADE NAME: Olecranonplate with Angular Stability

COMMON NAME: Bone Plate System

CLASSIFICATION: Plate, Fixation, Bone (see 21 CFR, Sec. 888.3030).

DEVICE PRODUCT CODE: HRS

SUBSTANTIALLY EQUIVALENT DEVICES Acumed Olecranon Plate (**K012655**)
Synthes Curved Reconstruction Plate (**K011334**)
Zimmer (**1974**) Zuelzer Hook Plate for fracture of the Olecranon

DEVICE DESCRIPTION: The I.T.S. Olecranonplate with Angular Stability is a low-profile universal left and right titanium 8, 10, and 12 hole plate with various length 4.2mm Cancellous self-tapping and head locking stabilization screws. Additional 3.5mm Cortical screws of various lengths are self-tapping and are interchangeable in use to lock the plate to the dorsal shaft of the ulna. The Olecranonplate is made from CP titanium according to ASTM F 67-00 and the screws are made from 6-4 alloyed titanium according to ASTM F 136-02. The plate and screws are surface conditioned with a TIODIZE, Type II preparation.

INTENDED USE: Indications for Use include fixation of complex intra- and extra- articular fractures, osteotomies, nonunions, malunions, Type 1, 2, 3, & 4 simple fractures, and Type 5a, 5b, 5c, & 6 complex fractures (comminuted) of the proximal ulna (olecranon). The I.T.S. Olecranonplate with Angular Stability is used to stabilize fracture(s) of the proximal ulna (olecranon) in the elbow.

BASIS OF SUBSTANTIAL EQUIVALENCE: The I.T.S. Olecranonplate with Angular Stability is substantially equivalent to the Acumed, Synthes, and Zimmer Olecranon plate systems.

SUMMARY OF SAFETY AND EFFECTIVENESS: The I.T.S. Olecranonplate with Angular Stability is shown to be safe and effective for use in fracture fixation of the proximal ulna (olecranon) in the elbow.

OCT 17 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

I.T.S. Implantat-Technologie-Systeme GmbH
c/o Al Lippincott
Engineering Consulting Services, Inc.
3150 E. 200th Street
Prior Lake, Minnesota 55372

Re: K052368

Trade/Device Name: Olecranonplate with Angular Stability

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: HRS

Dated: August 26, 2005

Received: August 29, 2005

Dear Mr. Lippincott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

Sincerely yours,


SM

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure



Indications for Use

510(k) NUMBER: _____

DEVICE NAME: OLECRANONPLATE WITH
ANGULAR STABILITY

INDICATIONS FOR USE:

The I.T.S. Olecranonplate with Angular Stability is a titanium implant fracture fixation system for stabilizing fractures of the proximal ulna (olecranon) in the elbow.


Indications for Use include fixation of complex intra- and extra-articular fractures, osteotomies, nonunions, malunions, Type 1, 2, 3, & 4 simple fractures, and Type 5a, 5b, 5c, & 6 complex fractures (comminuted) of the proximal ulna (olecranon).

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number 1052368

Concurrence of CDRH, Office of Device Evaluation (ODE)